Subject: PUBLI CCOMMENT ON FEDERAL REGISTER w: KILLING ANIMALS FOR EYE TESTS

Date: Wednesday, October 10, 2012 4:19:24 PM ET

From: Jean Public

To: NIEHS NICEATM, speakerboehner@mail.house.gov, HUMANELINES@HSUS.ORG, INFO@PETA.ORG

CC: info@idausa.org, INFO@MERCYFORANIMALS.ORG, INFO@FARMSANCTUARY.ORG, INFO@MAGAZINE.COM

THE PUBLIC WANTS ZERO ANIMALS USED IN EYE TESTS. USE HUMAN CELLS, WHICH ARE FARM TRUER AND INDICATIVE OF TRUE HARM TO PEOPLE'S EYES. THE ANIMALS EYES ARE NOT SIMILAR. I SEE NO REASON TO ABUSE ANY ANIMAL FOR THESE TESTS, WHEN HUMAN CELLS CAN BE USED MORE ACCURATELY. THIS COMMENT IS FOR THE PUBLIC RECORD. JEAN PUBLIC

[Federal Register Volume 77, Number 196 (Wednesday, October 10, 2012)]
[Notices]
[Pages 61610-61611]
From the Federal Register Online via the Government Printing Office [http://www.gpo.gov/]
[FR Doc No: 2012-24868]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Interagency Coordinating Committee on the Validation of Alternative Methods Evaluation Report and Recommendations for Identifying Chemical Eye Hazards With Fewer Animals; Availability of Report; Notice of Transmittal to Federal Agencies

SUMMARY: The NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) announces availability of an Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) test method evaluation report (TMER) that provides recommendations for identifying chemical eye hazards with fewer animals.

ICCVAM concludes that using a classification criterion of one or more positive animals in a three-animal test to identify chemicals and

products that are eye hazards will maintain hazard classification equivalent to that provided by current testing procedures, while using up to 50% to 83% fewer animals. ICCVAM recommends consideration of this classification criterion together with eye safety testing procedures that use a maximum of three animals per test substance. This recommendation also harmonizes the number of animals used for eye safety testing across U.S. regulatory agencies and international test guidelines.

The report and recommendations have been transmitted to Federal agencies for their review and response to ICCVAM.

FOR FURTHER INFORMATION CONTACT: Dr. William S. Stokes, Director, NICEATM, National Institute of Environmental Health Sciences (NIEHS), P.O. Box 12233, Mail Stop: K2-16, Research Triangle Park, NC 27709.

Phone: 919-541-2384, Fax: 919-541-0947, Email: niceatm@niehs.nih.gov.
Hand Deliver/Courier address: NICEATM, NIEHS, Room 2034, 530 Davis Drive, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Background: Eye safety testing procedures vary among U.S. agencies. Current testing procedures specified in the U.S. Code of Federal Regulations (16 CFR 1500.42) provide criteria and procedures for identifying eye hazards based on rabbit eye test results (CPSC,

[[Page 61611]]

2010); however, current testing procedures (16 CFR 1500.42) do not provide criteria to classify results obtained from a three-animal test. NICEATM, in collaboration with ICCVAM, conducted an analysis to determine classification criteria based on results from a three-animal test that would maintain hazard classification equivalent to that provided by current testing procedures (16 CFR 1500.42).

The process for developing the ICCVAM recommendations began with a critical review of the analysis (Haseman et al., 2011) and existing data by the ICCVAM Interagency Ocular Toxicity Working Group (OTWG). As part of ICCVAM's ongoing international collaborations, scientists from

the European Union Reference Laboratory for Alternatives to Animal Testing and the Japanese Center for the Validation of Alternative Methods served as liaisons to the OTWG. The analysis (Haseman et al.,
2011) was provided to the Scientific Advisory Committee on Alternative
Toxicological Methods (SACATM) at the June 17-18, 2010 meeting (75 FR
26758, May 12, 2010) for comment. The public was also given an opportunity to comment at that meeting. The OTWG then developed draft
ICCVAM recommendations regarding classification criteria based on results from a three-animal test that would maintain hazard classification equivalent to that provided by current testing procedures (16 CFR 1500.42). The draft ICCVAM recommendations and supporting analysis (Haseman et al., 2011) were made available on the
NICEATM-ICCVAM Web site (http://iccvam.niehs.nih.gov/methods/ocutox/reducenum.htm) for comment by the broad stakeholder community (76 FR
50220, August 12, 2011).

ICCVAM considered the analysis (Haseman et al., 2011), all public
comments, and the SACATM comments in preparing the final ICCVAM test
method recommendations. The recommendations are provided in the ICCVAM
Test Method Evaluation Report: Identifying Chemical Eye Hazards with
Fewer Animals (NIH Publication No. 12-7930), which is available on the
NICEATM-ICCVAM Web site (http://iccvam.niehs.nih.gov/methods/ocutox/reducenum-TMER.htm). ICCVAM concludes that using a classification criterion of one or more positive animals in a three-animal test to

identify chemicals and products that are eye hazards will maintain hazard classification equivalent to that provided by current testing
procedures (16 CFR 1500.42 [CPSC, 2010]), while using up to 50% to 83%
fewer animals. ICCVAM, therefore, recommends consideration of this classification together with eye safety testing procedures that use a
maximum of three animals per test substance. Consistent with ICCVAM's
duty to foster interagency and international harmonization (42 U.S.C.
285l-3), this recommendation harmonizes the number of animals used for
eye safety testing across U.S. regulatory agencies and international

test guidelines. The ICCVAM TMER includes relevant ocular toxicity regulations and guidelines, applicable Federal Register notices, public comments, and SACATM meeting minutes.

Background Information on ICCVAM, NICEATM, and SACATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods and integrated testing strategies with regulatory applicability and promotes the scientific validation and regulatory acceptance of testing methods that more accurately assess the safety and hazards of chemicals and products and that reduce, refine (enhance animal well-being and lessen or avoid pain and distress), or replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l-3) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts independent validation studies to assess the usefulness and limitations of new, revised, and alternative test methods and strategies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods and strategies for validation studies and technical evaluations. Additional information about NICEATM and ICCVAM can be found on the NICEATM-ICCVAM Web site (http://iccvam.niehs.nih.gov/).

SACATM was established in response to the ICCVAM Authorization Act (Section 285l-3[d]) and is composed of scientists from the public and private sectors. SACATM advises ICCVAM, NICEATM, and the Director of the NIEHS and NTP regarding statutorily mandated duties of ICCVAM and activities of NICEATM. SACATM provides advice on priorities and activities related to the development, validation, scientific review, regulatory acceptance, implementation, and national and international harmonization of new, revised, and alternative toxicological test methods. Additional information about SACATM, including the charter

,
roster, and records of past meetings, can be found at http://ntp.niehs.nih.gov/go/167.

References

CPSC. 2010. Federal Hazardous Substances Act Regulations. 16 CFR
1500. Available: http://www.gpo.gov/fdsys/pkg/CFR-2011-title16-vol2/pdf/CFR-2011-title16-vol2-chapII-subchapC.pdf.

Haseman J.K., Allen D.G., Lipscomb E.A., Truax J.F., Stokes WS. 2011. Using fewer animals to identify chemical eye hazards: revised criteria necessary to maintain equivalent hazard classification. Regul
Toxicol Pharmacol 61: 98-104.

Dated: October 3, 2012.
John R. Bucher,
Associate Director, National Toxicology Program.
[FR Doc. 2012-24868 Filed 10-9-12; 8:45 am]
BILLING CODE 4140-01-P